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WENDEROTH, LIND & PONACK  
SOUTHERN BLDG, STE 700  
805 15TH ST, NW  
WASHINGTON, DC 20005

18N1

EXAMINER

MARSCHER, A

ART UNIT

PAPER NUMBER

1807

9

DATE MAILED: 03/23/93

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

03/23/93

☒ This application has been examined ☒ Responsive to communication filed on 12-11-92 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                   |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/>  |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-23 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2. ☐ Claims \_\_\_\_\_ have been cancelled.

3. ☒ Claims 17-20, 22, and 23 are allowed.

4. ☒ Claims 1-16, 21 are rejected.

5. ☐ Claims \_\_\_\_\_ are objected to.

6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on \_\_\_\_\_, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Applicant's arguments filed 12/11/92 have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Claims 1-16 and 21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 3, the phrase "a chosen part" is cited. The rejection based on the unclear wording as discussed in the previous office action is reiterated and maintained. Applicant is hereby informed that the amendment filed 12/11/92 has not clarified this wording by amending in the phrase "oligonucleotides comprising". The practice of the word "chosen" still could either be directed to mean a segment of one of the oligonucleotides selected from those in a complete set or the practice of choosing one complete oligonucleotide from said complete set. Alternatively the array immobilized oligonucleotides may be simply different from one cell to another so that chosen versus complete set versus whole oligonucleotides is not a distinction that limits the claim practice. It is expected that all claim compositions are "chosen", for example, as part of an enabled invention. Clarification via further

amendment of the claim wording is requested.

In claim 2, line 6, and in other claims, the word "sequence" is cited as if it was a composition. A "sequence" is a characteristic of a nucleic acid and is not in itself a composition. This basis for vagueness and indefiniteness as discussed in the previous office action but neither responded to nor argued in the response of applicant filed 12/11/92.

What are the metes and bounds of the "pairs" of claim 3, line 2? What characterizes a "pair"?

Claim 21 cites a cell size of between 10 and 100 microns. Since the cells are on a surface, applicants must mean one of the dimensions as a limitation. It is unclear whether applicant means to claim a square shaped cell wherein the claim limitation directed to 10-100 microns is one side of said square. Alternatively, does applicant mean any irregularly shaped cell where 10-100 microns is the maximum linear dimension? Does applicant wish to claim a circular cell shape where 10-100 microns is the diameter of said cell? Clarification is requested.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, and 8-10 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Brigati et al.

This rejection is maintained and reiterated from the previous office action. Applicant has argued this rejection based on first summarizing the invention and then argued a fundamental difference between in-situ hybridization and the instant invention. The Examiner wishes to point out that a narrow reading of the instant specification and claims may be supportive of applicant's position but that examination of claim language is to be inclusive of the broadest reasonable interpretation of claim language. Such reasonable interpretation has been discussed in the previous office action. The fact that Brigati et al. utilizes the immobilized viral nucleic acids as targets does not prevent its function from being the same as the instant invention. The immobilized tissue samples contain surface area portions or "cells" that contain immobilized nucleic acids of different types, e.g. different virus types as listed in the last four lines of the abstract, the same as the instant invention. These types are chosen beforehand by the desire of the practitioner to probe for certain viral types, for example, and operationally chosen by probe hybridization. It is noted that the "cells" on the solid support are irregular in shape in Brigati et al. It is noted that the instant claims do not limit the shape of the claimed cells. The Examiner wishes to emphasize that the interpretation of "cells" in Brigati et al. is directed to surface regions wherein nucleic acid is immobilized. The fact

that these cell regions are derived from viral particles or possibly living cells from cell culture does not violate the claim language. Applicant additionally argues that the cells in their claim is obviously used in the "mathematical" sense. Such a mathematical sense is not reflected in the claim language. The citation of the word "array" does not cure this problem since there is no instant or art defined definition for "array" that limits it to "squares" or "circles" etc. It may be an irregular array of cells as practiced in Brigati et al. The labeling of instant claim 8 is practiced by Brigati et al. during the hybridization with labeled probe. In summary the rejection is deemed still proper..

Claims 1-4 and 8-11 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Saiki et al.

This rejection is maintained and reiterated as given in the previous office action. Applicant argues this rejection based on the lack of a complete set disclosure. This is non-persuasive in that nowhere in the instant disclosure is there a "complete set" definition of any kind. Therefore the set used by Saiki et al. is just as good a complete set as virtually any other set of oligonucleotides. Thus the rejection is maintained.

The disclosure is objected to because of the following informalities:

On page 20, line 6, the word "positons" appears to be misspelled.

In claim 19, line 9, the word "nucleotidfe" appears to be

misspelled.

Appropriate correction is required.

Claims 17-20, 22, and 23 are allowable because the array of different oligonucleotides covalently attached to the cells of the surface of a solid support is neither taught nor suggested by the prior art of record.

Claims 5, 7, 12-16, and 21 are allowable over the prior art of record for reasons of record.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

The CM1 Fax Center number is either (703) 308-4227 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*AM*

A. MARSCHEL:am

March 22, 1993

AMELIA BURGESS YARBROUGH  
PRIMARY EXAMINER  
ART UNIT 1807